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Karen Zielen
Name

May 27, 2004
Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: M.K. Carpenter et al.

Filing Date: June 21, 2001

Serial No: 09/888,309

Docket: 090/002

Title: DOPAMINERGIC NEURONS OBTAINED FROM HUMAN EMBRYONIC STEM CELLS

Art Unit: 1632

Examiner: Anne Marie Falk, Ph.D.

DECLARATION UNDER 37 CFR § 1.132

R. SCOTT THIES, Ph.D.

Commissioner for Patents
Alexandria, VA 22313-1450

Dear Sir:

I, SCOTT THIES, do hereby declare as follows:

1. I am a cell biologist who has been working in the field of regenerative medicine since 1989. Since 1997, I have been developing procedures to expand and characterize human neural cells. I joined Geron Corporation in March of 2001, and am currently Associate Director of Neurobiology. My project entails the expansion and characterization of neural progenitors from human embryonic stem cells for treatment of conditions such as Parkinson's Disease and Spinal Cord Injury.

A copy of my curriculum vitae accompanies this Declaration.

2. I have reviewed the patent application indicated above, along with the pending claims. The application describes methods and reagents for generating neural cells from pluripotent stem (hES) cells. Example 5 provides data from experiments in which human embryonic stem cells were differentiated into populations that were highly enriched for cells bearing markers of the neural lineage, such as β-tubulin , MAP-2, and tyrosine hydroxylase (Table 5, Figure 4).

3. I understand the Examiner has questioned how the combination of undifferentiated hES cells and hES derived neural cells is described in the disclosure, and how these cell populations can be used together.

4. The patent application describes reagents, techniques, and strategy for preparing and characterizing populations of specialized differentiated cells. This is referred to as a system, both in the Summary (page 4), and at the outset of the Detailed Description (page 7). The disclosure elaborates how to use the differentiated cells for a variety of purposes, including therapeutic treatment of neurological disease, and drug screening.

5. Someone skilled in the production of mammalian cells will understand from reading the disclosure that the "system" referred to encompasses the starting undifferentiated hES cell population, and the various populations that are obtained using the differentiation paradigms that are described and illustrated.

In particular, someone making neural cells by following some of the exemplified methods would begin with a line of undifferentiated hES cells. This meets the requirement of the first component of the claims. As the cells are guided along the neural differentiation pathway as described, they would acquire markers such as β-tubulin, MAP-2, or tyrosine hydroxylase. This meets the requirement of the "second population" indicated in the claims.

6. Someone practicing the invention in this way would therefore have possession of the undifferentiated hES cells, and possession of the cells bearing the neural markers, as part of the system for generating neural progenitor cells or terminally differentiated cells. The neural lineage cells would be suitable for a number of different uses described in the specification, such as the preparation of pharmaceutical compositions, and for use in drug screening.

7. It would not be necessary for the user to have possession of the two cell populations at the same time, since a population of undifferentiated hES cells could be caused to differentiate to neural cells in its entirety.

However, a scientist knowledgeable in this area understands the benefit of retaining some of the hES cells in the undifferentiated state, since the undifferentiated hES cells can be further expanded to act as a virtually unlimited reservoir for producing the differentiated cells. The use of the system in this way is provided in the Example section of this patent application. To this day, Geron Corporation continues to maintain hES cell lines in both the undifferentiated form, producing neural cells whenever needed in the quantity required.

8. I hereby declare that all statements made in this Declaration of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

5/27/04
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Ph.D., Duke University, Physiology, 1983

Honors and Awards

Honors Program, University of Miami, 1975-1979
Privileged Studies Program, University of Miami, 1976-1979
Alpha Lambda Delta, National Freshman Honors Society, 1976
Beta Beta Beta, National Biology Honors Society, 1977
Phi Kappa Phi, National Honors Society, 1978
Omicron Delta Kappa, National Honors Society, 1978
National Research Service Award, 1979-1983
Sigma Xi Grant-in-Aid of Research, 1980
Biomedical Research Support Grant, 1981
National Research Service Award, 1984-1986
Biomedical Research Support Grant, 1986
National Research Service Award, 1987-1989

Associations

Endocrine Society, Member, 1990-present
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Teaching Experience

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Professional Experience

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Postdoctoral Fellow, Division of Endocrinology and Metabolism,
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Radiation Safety Officer, Geron Corp., 2002-present

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Publications

Abstracts

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